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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ENDRE MARKOVITS SCHERSL,
ALEJANDRO MARKOVITS ROJAS, and MIGUEL FUENZALIDA DIAZ

Appeal 2009-003515
Application 09/922,532
Technology Center 1600

Decided: November 27, 2009

Before ERIC GRIMES, LORA M. GREEN, and FRANCISCO C. PRATS ,
Administrative Patent Judges.

GREEN, *Administrative Patent Judge.*

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 57 and 59-63. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

Claim 57 is representative of the claims on appeal, and reads as follows:

57. A method for lowering serum level of cholesterol comprising the step of orally administering a composition comprising a mixture of policosanols, said mixture consisting essentially of from about 1 % to about 5 % by weight of 1-eicosanol, from about 5 % to about 30 % by weight of 1-docosanol, from about 20 % to about 60 % by weight of 1-tetracosanol and from about 15% to about 50 % by weight of 1-hexacosanol.

The Examiner relies on the following evidence:

Cleary	US 4,495,094	Jan. 22, 1985
Fuenzalida	EP 0952208 A2	Apr. 22, 1999
Sorkin, Jr. (Sorkin)	US 5,952,393	Sep. 14, 1999
Milstein	US 6,394,230 B1	May 28, 2002
Gamble	US 6,596,776 B1	Jul. 22, 2003

Peter J.H. Jones et al., *Short-Term Administration of Tall Oil Phytosterols Improves Plasma Lipid Profiles in Subjects with Different Cholesterol Levels*, 47 METABOLISM no. 6, 751-56 (1998) (Jones).

We affirm.

ISSUE

The Examiner concludes that claims 57 and 59-63 are rendered obvious by the combination of Fuenzalida, Sorkin, Gamble, Cleary, Milstein, and Jones.

Appellants contend that the selection of the specific four policosanols as required by the method of claim 57 would not have resulted from routine experimentation with prior art mixtures containing eight or more components.

Thus, the issue on appeal is: Have Appellants demonstrated that the Examiner erred in concluding that the combination of Fuenzalida, Sorkin, Gamble, Cleary, Milstein, and Jones renders the method of claim 57 obvious?

FINDINGS OF FACT

FF1 According to the Specification, the “present invention is related to food and pharmaceutical compositions containing fatty alcohols of 26 or less carbon atoms per molecule such as octadecanol, eicosanol, docosanol, tetracosanol or hexacosanol and/or wood sterols useful for treating hypercholesteromia [sic, hypercholesterolemia] in human beings.” (Spec. 1.)

FF2 The Examiner rejects claims 57 and 59-63 under 35 U.S.C. § 103(a) as being obvious over the combination of Fuenzalida, Sorkin, Gamble, Cleary, Milstein, and Jones (Ans. 3). As Appellants do not argue the claims separately, we focus our analysis on claim 57, and claims 59-63 stand or fall with that claim. 37 C.F.R. § 41.37(c)(1)(vii).

FF3 The Examiner cites Fuenzalida, Sorkin, and Gamble for teaching that “policosanols, i.e., long chained aliphatic alcohols, are useful in lowering plasma cholesterol levels.” (*Id.*)

FF4 The Examiner finds that “Fuenzalida teaches the presence of fatty alcohols such as eicosanol, docosanol, tetracosanol and hexacosanol,” and that “Cleary teaches the presence of octadecanol in tall oil.” (*Id.*)

FF5 The Examiner relies on Gamble, Milstein, and Jones for teaching “the incorporation of the cholesterol-lowering agents, such as mixtures of aliphatic alcohols, into food substances such as margarine is known in the art.” (Ans. 3-4.)

FF6 The Examiner concludes that based on the teachings of the prior art as set forth above, “the utilization of a composition comprising long chained aliphatic alcohols in lowering plasma cholesterol levels would have been obvious to the skilled artisan in the art at the time of the present invention.” (*Id.*)

FF7 The Examiner notes that the “instant claims differ from the cited prior art by reciting specific ranges of eicosanol, docosanol, tetracosanol and hexacosanol with or without a specific amount of octadecanol,” but concludes that it would have been within the level of skill of the ordinary artisan to optimize the amount of each of the alcohols in the composition. (*Id.*)

FF8 The Examiner also notes that as the claim uses the transition term “comprising,” the “claims are not limited to the four recited policosanols but could include the other alcohols taught by the prior art.” (*Id.* at 5.)

PRINCIPLES OF LAW

The “phrase ‘consisting essentially of’ limits the scope of a claim to the specified ingredients and those that do not *materially affect the basic and novel* characteristic(s) of a composition.” *In re Herz*, 537 F.2d 549, 551-52 (CCPA 1976) (emphasis added); *see also PPG Indus., Inc. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998). Appellants bear the

burden of establishing that the basic and novel characteristics of the claimed invention would be materially affected by, or at least be reasonably expected to be materially affected by, any component or step of an applied reference that is argued to be excluded by a “consisting essentially of” transitional phrase used in the claims. *See In re De Lajarte*, 337 F.2d 870, 873-74 (CCPA 1964); *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (BPAI 1989).

ANALYSIS

Appellants argue that “the cited references, both singularly and in combination, do not teach, suggest, or anticipate the present composition^[1] and . . . effective amounts of policosanols.” (App. Br. 10.)

Appellants note that Fuenzalida teaches the presence of “fatty alcohols such as eicosanol, docosanol, tetracosanol and hexacosanol in tall oil,” but teaches that in cholesterol lowering diets, “reduced forms of sterols, known as stanols, are used.” (*Id.*) The policosanols compositions of Sorkin and Gamble, Appellants assert, while known to lower cholesterol, contain eight or nine different policosanols with carbon numbers ranging from 18 to 36, and not the four policosanols constituents of claim 57 with the number of carbons having a narrower range from 18 [sic, 20] to 26 (*id.* at 11).

Appellants argue that the subject matter of claim 57 represents a species of

¹ Appellants present a table in the Appeal Brief, Table 1, purportedly showing the different range of compositions in weight percent of policosanols from different sources (App. Br. 10). We note that the Table states that claim 57 requires octadecanol, but that octadecanol is not recited in claim 57. In addition, the weight percentages set forth for claim 57 in the Table for the other policosanols do not correspond to the weight percentages recited in appealed claim 57.

policosanols from tall oil “not previously known to possess . . . cholesterol lowering effects” from the genus of policosanols “which were known to possess cholesterol lowering effects.” (*Id.*)

Appellants assert that the chemical arts, coupled with the unpredictable physiological effects of chemicals, contradict the Examiner’s assumption “that ‘all’ plant alcohols, no matter the carbon number would have cholesterol lowering effects.” (*Id.*) According to Appellants, “there is substantial uncertainty on the effect of even small changes in the constituents of . . . policosanol mixtures on a mixture’s hypocholesterolemic activity.” (*Id.*) Appellants argue that “the art clearly demonstrates that the policosanol composition profile and source are critical in determining hypocholesterolaemic activity.” (*Id.* at 15.) Thus, Appellants argue, “the selection of the specific four policosanols of the claimed invention, in the amounts claimed, would not have resulted from routine experimentation with prior art mixtures containing eight or more components.” (*Id.* at 12.)

We have carefully considered Appellants’ arguments, but do not find them convincing. All of Appellants’ arguments ultimately rest on the contention that the ordinary artisan would not have been motivated to use just the four policosanols recited in claim 57, and that it would have been unpredictable that the use of only those four policosanols would have hypocholesterolemic activity.

As noted by the Examiner, however, the claims do not limit the mixture of policosanols only to the four specifically recited in the claims. Claim 57 requires a “mixture consisting essentially of from about 1 % to about 5 % by weight of 1-eicosanol, from about 5 % to about 30 % by

weight of 1-docosanol, from about 20 % to about 60 % by weight of 1-tetracosanol and from about 15% to about 50 % by weight of 1-hexacosanol.” The transition phrase “consisting essentially of” only excludes those ingredients that do not materially affect the basic and novel characteristics of a composition. In this case, the “basic and novel characteristic” is that the mixture has a cholesterol lowering effect, and the inclusion of additional policosanols, as taught by Fuenzalida, Sorkin, and Gamble, does not undermine that effect.

CONCLUSION OF LAW

We conclude that Appellants have not demonstrated that the Examiner erred in concluding that the combination of Fuenzalida, Sorkin, Gamble, Cleary, Milstein, and Jones renders the method of claim 57 obvious.

We thus affirm the rejection of claim 57 under 35 U.S.C. § 103(a) as being obvious over the combination of Fuenzalida, Sorkin, Gamble, Cleary, Milstein, and Jones. As claims 59-63 stand or fall with claim 57, we affirm the rejection as to those claims as well.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

dm

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Application 09/922,532

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